Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D1048233	06/21/2018
Name of Provider or Supplier	**Street Address, City, State**	
Medical Genetics Diagnostic Laboratory	Bldg 35 Room 1b203, Bethesda, MD	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D3027	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(1) Test requisitions and authorizations. Retain records of test requisitions and test authorizations, including the patient's chart or medical record if used as the test requisition or authorization, for at least 2 years. This STANDARD is not met as evidenced by: Based on review of one patient testing record and interview with staff, the laboratory failed to ensure either the written or electronic test requisition and authorization for patient testing of Holoprosenchaly (HPE) or Muenke Syndrome were maintained for at least two years. Findings include: Cross-reference D5301.
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on review of the laboratory protocol, run worksheet, deoxyribonucleic acid (DNA) films and interview with staff, the laboratory failed to have established policies for specimen tube labelling that ensured positive identification (ID) and integrity of patient't specimens during performance of runs for detection of HPE and Muenke's Syndrome. Findings include: 1. The surveyor reviewed one patient run for detection of Holoproencephaly (Patient Sample ID = CLIA 528) and found that during sample testing for HPE, fifteen (15) different amplicons across four (4) genes (SHH,

	ZIC2, TGIF and SIX3) are part of the lab's screening process 2. The fifteen amplicons are listed as follows: SHH exon (ex)1; SHHex2; SHHex3A; SHHex3B; SIX3ex1B; SIX3ex2; TGIFex1; TGIFex2; TGIFex3; TGIFex6A; TGIFex6B; ZIC2ex1A; ZIC2ex1B; ZIC2ex2 and ZIC2ex3. 3. During reivew of sample CLIA#528, there was 15 seperate DNA films labelled for each amplicon and seven (7) samples ran along with each film. 4. There was no system on the run worksheets to indicate how 105 specimen alliqot microtainer tubes were to be identified to keep positive patient ID and integrity during sample processing and testing phase of the assay. 5. During interview with the lab director and technical supervisor at approximately 2:00pm, there was admission that the lab had no such system and testing personnel were allowed to create their own labelling system during a patient run. They also admitted and film evidence showed that often more than one patient sample was tested during an assay run. 6. The lab director also admitted that all sixty (60) patient samples tested in the last twelve months were handled in the same manner.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of twice annual accuracy checks and interview with staff, the laboratory failed to have a written system to verify the accuracy of both the HPE and Muenke's system assays. Findings include: 1. The surveyor had described and shown evidence of twice annual accuracy checks by the technical supervisor. The technical supervisor described the process (and was shown use of via CLIA #528) as the first run of an suspect (rule/out-r/o) HPE or Muenke's case is a screening study, and if any of the suspect genes associated with either disease are positive, then the testing personnel repeat the study using only the amplicons positive on the screen. 2. The described procedure was not stated in their procedure manual. 3. During interview with the lab director and technical supervisor at approx. 2:15pm, there was an admission the staff could measure the accuracy of the assay at least twice annually, however this procedure was not described as such in their procedure manual. 4, The lab director also admitted that accuracy testing was handled in the same manner during years 2016 and 2017.
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of patient testing records, the procedure manual, and interview with staff, the laboratory failed to ensure requests for patient testing for mutational screening for holoprosencephaly and muenke's syndrome, included either a written or

	electronic request for patient testing from an authorized person (D5301) and have written and established specific monitors to periodically evaluate the overall quality of the preanalytic systems and correct problems in a timely manner when identified (D5391). Findings include: See D5301 and D5391.
D5301	TEST REQUEST CFR(s): 493.1241(a) The laboratory must have a written or electronic request for patient testing from an authorized person. This STANDARD is not met as evidenced by: Based on review of patient submission contents, the procedure manual and interview with staff, the laboratory failed to ensure it had a written or elecronic request for patient HPE screening for fourty-three (43) samples received for testing, from March 27, 2016 through the date of the survey, from an authorized person. Findings include: 1. The surveyor's review of 60 samples submitted from March 27, 2016 to the date of the survey, 43 samples (CLIA #s 482 - 487, 489, 495, 503 - 507, 509-525 and 528-542) did not contain either a written or electronic request for patient testing from an authorized person. 2. The lab procedure stated only that related to Test Request Instructions, "The request to perform a laboratory test must be a written order generated by the requesting physician/genetic couselor." 3. Interview with the lab director, clinical consultant and technical supervisor at approximetely 11:00am confirmed the lab was relying on the genetic counselor's submitted medical history, clinical manifestations documentation and patient consent for testing, as the written /electronic request. It was also admitted that all 60 patient samples tested since March 27, 2016 were received with a genetic counselor's request.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on review of the laboratory Quality Assessment (QA) Plan and interview with staff, the laboratory failed to have written policy and procedures in the form of pre-analytic monitors which would monitor, assess, and if needed, correct problems identified with their not ensuring a written or electronic request for HPE or Muenke Syndrome testing, was received prior to patient testing. Findings include: Cross-reference D5301.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in

	493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of patient testing records, the procedure manual, and interview with staff, the laboratory failed to have documented laboratory testing records for mutational screening for holoprosencephaly and muenke's syndrome, that included: (1) written procedures describing the type, identify, number, frequency of positive controls incorporated into the patient runs, limits of acceptability and the process to retrieve and interpret results of parts of the testing process not performed in-house (D5403); (2) the analytic system produced accruate results when changes were made to streamline the sequencing procedure (D5423); (3) the quality control system included positive quality controls during both the screening extraction processes (D5453) and, (4) molecular aplification processes of the assays (D5455); (5) twice annual parallel testing for two thermocyclers used during patient testing (D5775); and (6) have written and established specific monitors to periodically evaluate the overall quality of the preanalytic systems and correct problems in a timely manner when identified (D5791). Findings include: See D5403; D5423; D5453; D5455; D5775 and D5791.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: A. Based on review of the procedure manual, run worksheets, DNA films and interview with staff, the laboratory failed to ensure the testing protocols for HPE and Muenke's Syndromes included a description of how to uniformily label sample microtainers during analytic phase of testing. Findings include: 1. The surveyor reviewed the "Mutation Screening Protocol" dated as approved by lab director on June 11, 2018, and noted in Section 8. PCR PROTOCOL 'General Guidelines for PCR Set-Up-Procedure' at 8.3.4. "Label tubes or plate appropriately. Reaction can be performed in individual 0.2 ul tubes or on 96-well plate depending on the number of samples." lacks specific tube labeling instructions to the testing personnel if you microtain tubes or a plate map if using the 96-well plate. 2. Interview with the lab

	director and technical supervisor at approximely 3:15pm confirmed the findings. 3. Cross reference D5203. B. Based on review of the procedure manual, run worksheets, DNA films and interview with staff, the laboratory failed to ensure the testing protocols for HPE and Muenke's Syndromes included a description of the preparation of positive controls. 1. The surveyor reviewed the "Mutation Screening Protocol" dated as approved by lab director on June 11, 2018, and noted in Section 6. CONTROL "All controls are tested and analyzed in the same manner as patient samples. Positive controls are run in conjunction with patients to check specimen preparation methods, reagents, and instrument performance. Use a mutation specific positive control if the test is for confirmation of known/reported mutation. Use gene-specific positive control when screening for unknown mutation." 2. Interview with the lab director and technical supervisor at approximately 3:20pm there was an admission that procedures to prepare the postive controls were not included in the procedures. C. Based on review of the procedure manual, run worksheets, DNA films and interview with staff, the laboratory failed to ensure the testing protocols for HPE and Muenke's Syndromes included a description of control procedures. 1. The surveyor reviewed the "Mutation Screening Protocol" dated as approved by lab director on June 11, 2018, and noted in Section 6. CONTROL "All controls are tested and analyzed in the same manner as patient samples. Positive controls are run in conjunction with patients to check specimen preparation methods, reagents, and instrument performance. Use a mutation specific positive control if the test is for confirmation of known/reported mutation. Use gene-specific positive control when screening for unknown mutation." 2. Interview with the lab director and technical supervisor at approximately 3:20pm there was an admission that a description of control procedures within each patient run were not included in the procedures. D. Based on review of the procedure manual, run worksheets, DNA films and interview with staff, the laboratory failed to ensure the testing protocols for HPE and Muenke's Syndromes included a description of performing data analysis using the Mutation Surveyor program in the post analytic phase of testing. 1. The surveyor reviewed the "Mutation Screening Protocol" dated as approved by lab director on June 11, 2018, and noted there was no section or description of the data anaylsis using the Mutation Surveyor program in the procedure manual. 2. Interview with the lab director and technical supervisor at approximately 3: 30pm confirmed this finding.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on review of the procedure manual and interview with staff, the laboratory failed to record in writing, the accuracy, precision, analytical sensitivity, analytical specificity, reportable range (if applicable), reference range (if applicable) and any

	other performance characteristic deemed appropriate for test performance, each time the established testing protocol for HPE and/or Muenke's Syndrome was modified by the staff. Findings include: 1. When asked by the surveyor if the lab had modified or changed it's established testing protocols for either HPE and/or Muenke's Syndrome, the technical supervisor stated that an update to the HPE Mutation Sequencing SOP was made during the fall of 2016 and approved for use on December 16, 2016. This change involved incorporating the use of M13-tailed primers for gene amplication to streamline sequencing procedures for use with Universal M13 Forward (F) and Reverse (R) oligonucleotides. 2. The surveyor could not find written documentation of the effect of incorporating the use of M13-tailed primers for gene amplication on the protocols prior to actual patient testing. 3. During further interview with the lab director and technical supervisor at approximately 2:40pm, there was an admission the lab did not have written documentation, signed by the lab director, of the effects of change(s) made in the fall of 2016 on either HPE or Muenke's Syndrome protocols that incorporated the six (6) components under this regulation at 1253(b)(2)(i)-(vii). 4. The technical supervisor further admitted to the surveyor that he/she was unaware of the requirement to document any changes to established protocol/lab methods in writing for approval by the lab director.
D5453	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(iv)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each test system that has an extraction phase, include two control materials, including one that is capable of detecting errors in the extraction process; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the procedure manual, a run worksheet and interview with the staff, it was determined the laboratory failed to include, in one of one patient test run (Sample CLIA #528) for HPE reviewed, when the test method included an extraction phase, include two control materials, one negative and one capable of detecting errors in the extraction process and ensure that the inclusion of both controls was documented as performed. Finding include: 1. The surveyor reviewed the test run which included sample CLIA #528 and noted that the lab was only included a no template control (NTC) when testing patients with unknown mutations and there was no positive control sample on the run. 2. During interview with the lab director and technical supervisor at approximately 1:30pm, there was an admission that the staff regularily did not include any positive control that could detect errors during the extraction phase and documentation showed the inclusion of only the NTC on patient runs (including CLIA #528). 3. Cross-reference D5403.
D5455	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(v)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each molecular amplification procedure, include two control materials and, if reaction inhibition is a significant source of false negative results, a control material

	capable of detecting the inhibition. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the procedure manual, a run worksheet and interview with the staff, it was determined the laboratory failed to include, at least once each day patient samples are tested, in one of one patient test run (Sample CLIA #528) for HPE reviewed, each molecular amplification procedure includes two control materials, and if reaction inhibition is a significant source of false negative results, a control material that is capable of detecting the inhibition, and ensure that the inclusion of such controls was documented as performed. Finding include: 1. The surveyor reviewed the test run which included sample CLIA #528 and noted that the lab was only included a no template control (NTC) when testing patients with unknown mutations and there was no positive control sample on the run. 2. During interview with the lab director and technical supervisor at approximately 1:30pm, there was an admission that the staff regularily did not include any positive control that could detect errors during molecular amplification procedure(s) and documentation showed the inclusion of only the NTC on patient runs (including CLIA #528). 3. The lab director and technical supervisor further explained that reaction inhibition is not a significant source of false negative results, since the inclusion of kit based extraction steps and the evolution of more specific primers, have improved accuracy while eliminating virturally all sources of cross-reactivity. 4. Cross-reference D5403.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on review of the QA lab checklist, testing records and interview with staff, the lab failed to ensure, when that it's two Veriti 96-well Thermal Cyclers, placed into service in 2016, evaluations were performed between such equipment twice a year and there was documentation of the results of such comparison activities. Findings include: 1. The surveyor reviewed a CLIA Lab Checklist Document dated 2008 that was attached to the Lab QA Plan. Under the Analytic section on page 2 of the Checklist, there was the following statements to be confirmed by lab staff for each CLIA survey "___Lab maintains record of information contributing to test result for 2 years on a manner that can be readily retrieved." The fifth requirement under the sub-header of INSTRUMENTATION lists '___Documentation of comparison of duplicate instruments' 2. There was no documentation of twice a year comparisons between two Veriti 96-well Thermal Cyclers (S/N 2990233079 obtained on July 11, 2016 and S/N 2990234707 obtained on September 27, 2016) in 2016, 2017 and 2018 (to the date of the survey). 3. Interview with the lab director and technical supervisor at approximely 3:10pm confirmed this requirement for comparisons was not performed.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)

	(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory Quality Assessment (QA) Plan and interview with staff, the laboratory failed to have written policy and procedures in the form of specific analytic monitors that would monitor, assess, and if needed, correct problems identified in the analytical phases of patient testing for HPE or Muenke Syndrome testing, assuring quality laboratory processes during patient testing. Findings include: Cross-reference D5203, D5217, D5403, D5423, D5453, D5455 and D5775
D5817	TEST REPORT CFR(s): 493.1291(i) If a laboratory refers patient specimens for testing-- (i)(1) The referring laboratory must not revise results or information directly related to the interpretation of results provided by the testing laboratory; (i)(2) The referring laboratory may permit each testing laboratory to send the test result directly to the authorized person who initially requested the test. The referring laboratory must retain or be able to produce an exact duplicate of each testing laboratory's report; and (i)(3) The authorized person who orders a test must be notified by the referring laboratory of the name and address of each laboratory location where the test was performed. This STANDARD is not met as evidenced by: Based on review of the procedure manual, a sample lab report and interview with laboratory staff, it was determined the laboratory, when it refers patient samples for testing, as required in it's performance of the HPE sceening protocol, failed to notify the authorized person who ordered the test for sample CLIA #528, that a part of the testing process was referred for further testing and listed the name and address of each laboratory where such test(s) was/were performed. Findings incude: 1. During a walkthru of patient sample processing, the technical supervisor mentioned that after DNA amplication, there is a second PCR clean-up step involving via enzymatic process (ExoSap Program) and then the patient's DNA is sent out to a reference laboratory (Eurofins - Located in Louisville, Kentucky - having CLIA No. 18d2099108) additional sequencing. 2. The surveyor reviewed the patient report for CLIA #528 and noted that it did not state the name/address/CLIA number of the reference laboratory, nor did the report state what steps of the method were performed at the outside facility. 3. During interview with the lab director and technical supervisor at approximately 3:45, there was an admission that the staff was unaware of the requirement in this subpart to identify the name/address/CLIA No. and what part (s) of the testing process were performed by an outside laboratory. 4. The director and technical supervisor also admitted that besides CLIA #528, all other 59 samples performed between March 27, 2016 and the date of the survey, were reported without the identity of the outside laboratory were additional DNA sequencing steps were performed.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441

	The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of patient testing records, the procedure manual, and interview with staff, the laboratory director failed to ensure the test systems developed and used in the facility for mutational screening for holoprosencephaly and muenke's syndrome, provided for: (1) the quality of laboratory services through the pre-analytic and analytic phases of testing (D6082); (2) the quality control (D6093) and (3) quality assessment programs included appropriate monitors and are maintained to assure the quality of the laboratory services (D6094); (4) the maintenance of established acceptable levels of analytical performance for each test system (D6095). Findings include: See D6082; D6093; D6094 and D6095.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual and interview with the laboratory director, it was determined the director failed to ensure the lab study protocols developed and used in patient testing processes to screen for HPE and Muenke's Syndrome, assurred the lab provided quality services for all aspects of the the test(s) performance and included the pre-analytic, analytic and post-analytic phases of testing. Finding include: Cross-reference D5203 and D5403.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual and interview with the laboratory director, it was determined the director failed to ensure the lab had an appropriate quality control program established with monitors developed and that were being maintained to assure the quality of lab services provided and could identified failures in such quality in the analytic phase of testing as they occurred. Finding include: Cross-reference D5453 and D5455.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)

	The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the laboratory QA Plan and interview with the laboratory director, it was determined the director failed to ensure the lab's QA Plan had established monitors developed and were being maintained which assured the quality of lab services provided and identified failures in such quality in both the pre-analytic and analytic phases of testing as they occurred. Finding include: Cross-reference D5391 and D5791.
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6) The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. This STANDARD is not met as evidenced by: Based on review of the laborotory procedure manual and interview with the lab director, it was determined the director failed to ensure any and all changes or modifications to established study protocols or procedures, met established parameters of acceptable levels of analytic perforamance and were appropriate documented and signed off as approved for use prior to patient testing. Findings include: Cross-reference D5423. During interview with the lab director at approximately 3:30pm, there was an admission that the technical supervisor had shown him the data where the lab had verified protocol accruacy from the changes made during the fall of 2016, but the requirements under 1253.(b)(2)(i)-(vii) were never documented or signed off as approved, prior to such changes being used during patient testing.
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results. This STANDARD is not met as evidenced by: Based on review of the laborotory procedure manual and interview with the technical supervisor, it was determined the technical supervisor failed to ensure any and all changes or modifications to established study protocols or procedures, met established parameters of acceptable levels of analytic perforamance and were appropriate documented and approved for use by the lab director prior to patient testing. Findings include: Cross-reference D5423.
D6168	TESTING PERSONNEL CFR(s): 493.1487

	The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on review of personnel records and interview with the Laboratory Director and Technical Supervisor, the current testing individual (TP1), who started in the laboratory in June 2017, has not earned a doctoral degree from an accrediated instituation (D6171). Findings include: See D6171.
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality

	control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on review of personnel records and interview with the Laboratory Director and Technical Supervisor, it was determined the sole testing individual (TP1) who started work in the facility in June 2017, did not have evidence they earned their doctoral degree from an accredited institution. Findings include: 1. Personnel records for TP1 showed an earned doctoral degree in the field of Human Health Sciences at the Graduate School of Medicine, Kyoto University, Japan, on May 25, 2015. 2. There was no record that indicated TP1's doctoral degree was equivalent to an earned doctoral degree from an accrediated institution in the United States. 3. During interview with the LD and TS at approximately 9:45am, there was an admission the laboratory did not pursue getting an equivalency performed and documented on TP1's foreign doctoral degree.